A White Paper Response to the Proposed EPA Mitigation Measures on Rodenticides of 1/17/2007

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1.0 Position Summary

There is a continuing need for effective and affordable rodenticides for consumer-residential use as part of integrated pest management of commensal rodents. The public health benefits of these products clearly outweigh the potential risks. EPA has failed to consider the risks that will be presented by its own proposal if implemented. The second-generation anticoagulant rodenticide products that EPA proposes to reclassify as restricted use were specifically developed as replacements for first-generation products following the growth of widespread resistance to such products during the 1970s.

EPA's proposal would force consumers and others to return to the use of the less-effective and out-moded first-generation products. The Agency's proposed limitations on where and how consumers can use these less efficacious products will increase rodent problems. This will increase the danger to public health and well-being, and ironically increase the demand for and use of rodenticides in more accessible areas. The proposals ultimately will put the public at greater risk from pest rodents while increasing rodenticide risks to children and non-target animals.

The extensive history of use, efficacy, toxicity and hazard information already available for the second-generation products (and brodifacoum in particular) does not support reclassifying consumer use products as restricted use and removing them from the retail market. The justifications for the mitigation measures proposed by EPA are based upon speculation and assumptions, and EPA has failed to adequately consider alternative mitigation measures to address its concerns. The Agency's proposal treats all products similarly (without regard to its end product composition, labeling and package size and contents).

The proposed mitigation measures are overly simplistic and are unlikely to reduce the potential risks associated with rodenticide use in the United States. The forced shift to bait stations and paraffin block formulations will result in pest control failures, further enhancing conditions for selection of resistant species. Moreover, there will not be significant reduction in risk to non-target animals, and greater risk to the public from increased rodent populations will result.

The Agency's proposals are out-of-sync with well-established biological principles. The proposals ignore the expanding urban development and deteriorating conditions in many U.S. municipalities and the loss of financial resources to address the ever-increasing pest rodent problems, putting countless urban residents at greater risk from rodents. There are better (alternative) mitigation measures that can be recommended that would sustain rodent control and protect the public while ensuring responsible use of rodenticides.

1.1 Public Health and Economic Impacts When Commensal Rodents Are Not Adequately Controlled

The proposed EPA mitigation measures do not adequately assess and evaluate the public health and economic impacts if pest rodents cannot be controlled effectively and affordably. The three commensal rodent pest species in the US are the Norway rat (*Rattus norvegicus*), the Roof rat (*Rattus rattus*), and the house mouse (*Mus musculus*). These species were spread by human commerce from their habitats in Asia and the Middle East to Europe, and then to the New World in the 17th and 18th centuries. These invasive species are well adapted to living in and around human habitation, consuming food and feed. Rodent gnawing and burrowing causes extensive damage. Dams and levees can be weakened, electrical lines and cables can be cut (often causing fires), damage occurs to insulation within the walls of structures, and food and goods can be damaged and contaminated with feces and urine. Pest rodents cause the destruction and loss of other wildlife including endangered species (Whitmer, Campbell and Boyd, 1998). The total cost from pest rodents in the US in terms of environmental impacts and economic costs has been estimated at $19 billion per year, far more than any other invasive animal species (Pimentel, et al., 2000).

Pest rats and mice are prolific, even allowing for deaths due to predation and disease. It has been estimated (Jackson, 1982) that the average female house mouse can produce 30-35 offspring in a year, and live for about one year. A study beginning with a captive colony of 24 mice with abundant food and harborage grew to 2,000 mice after only 8 months (Corrigan, 2001). Norway rat females typically wean about 20 young per year (Jackson, 1982). The Norway rat will live a year or less and females typically wean about 20 young a year (Jackson, 1982). A typical rat infestation will consist of a dominant male, a breeding female, and upwards of 12 juvenile rats (Corrigan, 2001) that can grow to 50 rats or more in 5-6 months. Norway rats continually expand from their original sources to fill nearby available habitat. This potential to colonize underscores the need for sustained and effective rodent control efforts in many urban structures including apartment buildings and single-family homes.

Rodents have been responsible for some of the most devastating disease outbreaks in recorded history and have been responsible for over 10 million deaths in the past century alone (Corrigan, 2004). They are known to carry over 55 diseases, including viral, bacterial, protozoan and other pathogens. Some of the most common transmitted diseases associated with rats and mice include food poisoning, leptospirosis, Lyme disease, rickettsial pox, and trichinosis (Gratz, 1994). Lymphocytic meningitis, an emerging disease of children, has been identified in a large percentage of house mice from inner-city areas of several communities in the U.S. (Childs, 1992; Foster, et al, 2006).

Some diseases can be spread to people and other animals by contact with infected rodent urine and feces. A house mouse deposits up to 3,000 micro-droplets of urine in a 24 hr period (Bronson, 1979). A study in 2000 found that rats and mice play important roles in causing asthma and allergic rhinitis in individuals in inner-city homes. This study from eight metropolitan areas collected nearly 2000 dust samples from the homes of over 600 asthmatic children and found mouse allergens in 95% of the homes, while skin tests showed sensitivity to mice in 18% and to rats in 20% of the children (Phipatanakul, 2001).

It is in metropolitan areas, in particular, where the density of both people and rodents can lead to troubling interactions. Contact with pest rodents can result in bites. Studies of animal bites are commonly conducted because of concerns with rabies. Commensal rodents in the US are not known to carry rabies (Childs, et al, 1997), but published reports have shown that rodent bites often involve children, and can result in considerable trauma and occasionally lead to infections and disfigurement. Although national statistics are not currently available, A CDC survey of rat bites in 15 municipalities across the USA reported a total of 8,433 during the period 1971-1972 (Moore et al, 1977), approximately 4,200 bites yearly. More recently, a study examining records over nearly a 4-year period (1/1991 through 9/1994) found 514 reported rodent bite cases, in the five New York City boroughs (Childs et al, 1997); greater than 125 bites each year. A study in Philadelphia (Hirschhorn & Hodge, 1999) recorded 622 rat bite cases from 1974 to 1996, for an average of 28 bites per year. Based upon estimates of populations in U.S. urban areas, and allowing for underreporting of rat and mouse bites (due to the nature of the study and its focus on rabies), it can be estimated reasonably that 10,000 people, or more, are bitten yearly. Children of African-American and Hispanic origin are represented disproportionately as experiencing a higher number of rat bites (Hirschhorn & Hodges, 1999). Most bites were to the extremities of children, most often in the home while they were sleeping (Hirschhorn & Hodges, 1999; Ordog et al, 1985).

Urban sprawl, aging infrastructure and urban congestion are all increasingly contributing to the growing problems with rodent infestations. Rats are good swimmers and will freely use sewers and drains as a means of travel. A Boston study in residential neighborhoods with older brick sewers (the most common construction through the mid-1950s) found that 38% of sewers had rat activity (Colvin, Swift & Fothergill, 1998), and rats were found active in other underground systems, such as those housing phone and electric lines. Rats can withdraw into sewers to escape predation and control efforts, or to avoid winter weather in northern areas. A study in Philadelphia (Hirschhorn & Hodge, 1999) observed that Norway rats were traveling throughout neighborhoods in the sewers. Further, that study documented that areas with more unemployment and poverty had the highest incidence of rat bites. Vegetation and landscaping in cities can encourage rodent infestations. A study in Boston (Colvin, DeGregorio & Fleetwood, 1996) noted dense stands of vegetation and the presence of litter were strongly associated with the presence of rats. Shortcomings exist even in the design and engineering of new structures and infrastructure due to a lack of understanding of basic biological principals, and this continues to contribute to rodent problems (Colvin, 2002).

While sanitation and exclusion are useful preventative measures, it is not possible in much of the urban environment for individual homeowners to make sufficient improvements to their immediate surroundings and neighborhoods to limit rodent pressures. The urban trend has been toward expansion, more congestion, abundant food establishments, reduced sanitation, and aging infrastructure, and economically depressed neighborhoods. Urban neighborhoods typically have an underground network of sewer and drain lines that spread the rodent problem and continue to maintain close proximity between rats and people. It has become prohibitively expensive for municipalities in any organized fashion to address these many factors that contribute to a growing rodent problem in many U.S. cities, a problem that is predicted to progressively worsen during the 21st Century. The burden will fall on residents to try to maintain their personal well-being, with whatever tools are at their disposal.

Surveys have indicated that greater than 50% of homeowners do their own pest control (Kaukeinen, 1994), and that number is expected to increase. Unfortunately, at a time when rodent problems are expanding in urban areas throughout the U.S., there is a shortage of pest rodent experts (Colvin and Jackson, 1999). The lack of available experts is expected to be a major issue in the future as cities age and rodent problems concurrently increase during the 21st Century. Presently, there is no university laboratory in the U.S. with the capability to evaluate rodent control products, and the EPA's own rodent lab also has been closed. Consequently, there no longer is any university in the U.S. specializing in applied pest rodent biology and no institution providing specialized training in an academic setting which can produce graduates specializing in urban rodent control (Colvin, 2000). While the U.S. enjoyed a dominant world position with pest rodent technology development and study programs at the University of California at Davis and Bowling Green State University in Ohio from the 1960s through the 1980s, these specialized programs ended about 20 years ago. As a result, there is a knowledge vacuum that will continue to inhibit technology development and training of future pest rodent experts. The remaining knowledgeable people in the U.S. who worked through the problems with earlier rodenticides and developed modern rodent control methods and materials to combat resistance are now few and nearing retirement (if not actually retired).

The effective methods and materials developed to combat rodents and resistant species reflect extensive research, years of development, and international review spanning three decades and that considered carefully numerous factors including efficacy and potential risk. Such investigative and technical resources no longer are available. Moreover, the EPA's proposed risk mitigation methods, combined with existing and future trends in rodent problems, urban land use and infrastructure, and de-funding of control programs only can be expected to exacerbate national pest rodent problems in the future.

1.2 Warfarin Resistance and the Basis for the Development of Second-Generation Anticoagulant Rodenticides

Rodenticides offer an economical and effective approach to the control of pest rodents. These pests normally accept rodenticide baits under a range of conditions and circumstances. The currently available rodenticides have been classified and used successfully as general-use pesticides for many years and have been tested extensively (Kaukeinen & Rampaud, 1986). The current range of products pose very little hazard to non-target animals when the products are used according to label directions.

Warfarin ("first-generation" anticoagulant rodenticide) ushered in the modern age of rodent control in the 1940s, replacing more hazardous rodenticides with its lower hazard, antidote, low concentration, and multiplefeed action. In the 1970's, genetic resistance to warfarin was discovered in the USA in wild Norway rats (Jackson & Kaukeinen, 1972) and subsequently with roof rats and house mice (Ashton & Jackson, 1984). Funding from what is now the Centers for Disease Control generated survey data from locations in 30 states (Jackson et al, 1985). The survey demonstrated that warfarin resistance had developed independently at significant levels in samples from populations of Norway rats in 18 localities, house mice in 12 localities and roof rats in 9 localities (Ashton & Jackson, 1984; Jackson et al, 1985). Applicators in these areas noted a significant decline in the performance of first-generation anticoagulant baits (e.g., warfarin), leading to an inability to control rodent problems. However, use of brodifacoum bait

against rats documented to be warfarin-resistant resulted in effective control in both laboratory and field trials (Apperson, Sanders & Kaukeinen, 1981); similar results have been obtained in other studies (Quy, et al, 1995).

Anticoagulant resistance in rodents in the USA has been largely an urban phenomenon, because this is where the greatest selective pressure has been brought to bear on pest rodents (Jackson & Ashton, 1992). As a response to warfarin resistance, researchers produced the second-generation anticoagulants, such as bromadiolone, brodifacoum and difethialone (Buckle, 1994). These active ingredients worked for controlling rats and mice resistant to warfarin and the other first-generation anticoagulant rodenticides, such as diphacinone and chlorophacinone. Products containing the second-generation actives became dominant in the 1980s and 1990s, and warfarin-containing products largely disappeared from the professional marketplace. This process was hastened by the finding that a single feeding of these new products normally produced a lethal dose, eliminating the need for chronic use of first-generation anticoagulant rodenticides with their need for successive feedings.

The discovery and investigations of warfarin resistance in the USA were coincident with vastly expanded federal funding for urban rat control with more than $165 million provided between 1969 and 1985 (supplemented by $193 more in matching local funds). This expenditure involved a coordinated approach to reducing rat infestations in selected inner-city areas in over 100 communities and achieved notable successes (Ashton & Jackson, 1984). However, a move from federally-funded to state-funded programs in the Reagan years caused the reversal of much of this progress, with cities reverting to complaint-response programs and limited, generalized efforts at environmental education (Ashton & Jackson, 1984). Cities today are in many cases in worse condition in terms of rat populations than during the years of federal rat control programs, and more of the responsibility for local rodent control is necessarily placed now on the individual resident. The loss of effective rodenticides to these users could be tragic.

Warfarin and other first-generation anticoagulant products are problematic for use against wild rat and mouse infestations today. Studies in Chicago involving tests of rats trapped in resistance areas showed that the incidence of warfarin resistance of 67% observed in the 1970s had increased to 85% resistance a decade later, although warfarin was no longer being used (Jackson & Ashton, 1992). Studies in Boston with Norway rats captured in utility manholes revealed an incidence of warfarin resistance in feeding tests in 13.6% of one sample, and in 17.8% of another, although no sewer baiting program involving warfarin had been conducted previously (Colvin, Swift & Fothergill, 1998).

There has been little reason to conduct other warfarin-resistance surveys, because the second-generation anticoagulant rodenticides have been effective in removing resistant rodent populations. However, there is a high likelihood that the genes for warfarin resistance are still widely present in wild rat and mouse populations, and that there would be rapid selection for these genes if widespread warfarin use were renewed due to the reclassification of second-generation products for restricted use. Consumers buy and use a quantity of rodenticide comparable to that purchased by professional users (Kaukeinen, Spragins & Hobson, 2000); thus, the return to greater use of first-generation anticoagulants by consumers would produce significant selective pressure to isolate genetic resistance again as it did previously. Users would

experience efficacy failures using the older anticoagulants due to increasing resistance, as happened before the second-generation anticoagulants were developed.

Surveys of anticoagulant-resistant rats in England and Wales during 1988-1995 found a high prevalence of resistance to warfarin remaining in several regions after widespread use of other products, but did not find evidence of resistance to brodifacoum (MacNicoll et al, 1996). Similar work in Germany and elsewhere has found warfarin-resistant rodents, although no resistance has been noted anywhere in the world to the widely used products containing brodifacoum, after more than two decades of continued use (Corrigan, 2001).

Theories that warfarin resistance in the U.S. has been overstated (and can be addressed with first-generation anticoagulant products) rely on laboratory tests with rats first screened on warfarin or tests of offspring from surviving rats. One such theory postulates that different gut flora provide different sensitivities to warfarin in different rat populations, and that such flora can be overcome with the addition of strong antibiotics in baits (Poche, 1998). This theory has remained unproven and ignores the genetic transmission of the altered physiology that allows such 'super rats' to maintain blood homeostasis while eating anticoagulants. Moreover, including antibiotics in rodenticides would seem to be a very questionable strategy in view of the potential for unintended environmental effects.

A theory cited by the EPA in support of continued use of warfarin or other first-generation anticoagulant rodenticides involves a study of repeating feeding studies with wild resistant Norway rats in the laboratory and noting some mortality upon no-choice re-exposure to warfarin (Frantz & Madigan, 1998). In actuality, the resulting mortality was only 14-18% for survivors from the Chicago resistance site, which would hardly be significant if the same results were obtained in use against field populations. Lab tests with wild-trapped rats from mixed locations found 60 to 83% mortality with re-testing after one to six months of holding time. Wild rats do not respond well to captive conditions, and it is hardly surprising that months of lab holding and retesting (as many as four times in some cases) led to mortalities. There is no practical application or verification of such findings to the field, where rodenticide applications cannot be phased or presented without available, alternative foods. Studies have shown that if field control efforts do not produce at least 90% kill of rats, their numbers can quickly rebuild (Kaukeinen, Spragins & Hobson, 2000). Improved techniques that supplant the older feeding studies to identify genetic resistance in the lab and field have been introduced (Buckle, Prescott & Ward, 1994). Currently, these techniques include blood coagulation tests (Prescott & Buckle, 2000) and DNA evaluations (Pelz, et al., 2005).

Recent tests (Prescott & Kaukeinen, 2006) revealed that a currently available warfarin rodenticide product in the U.S. achieved an unacceptably low level of mortality with warfarin-resistant rodents, despite the prolonged test periods of 21 days of no-choice feeding for mice and 6 days for rats. Mice survived exposures to 15 to 26 times the expected lethal dose, and rats survived from 33 to 55 times their expected lethal dose of warfarin, indicating high levels of resistance that would not be addressed by continued use of first generation anticoagulants. Against the same strains of resistant rats and mice, a brodifacoum rodenticide product was achieved complete mortality against both resistant species in a 2-day test.

Warfarin resistance has been demonstrated previously to develop independently at widespread locations. This resistance, if selected for again, could have a major effect on efficacy against other first-generation anticoagulants with rats, and especially, against house mice (which have become the dominant commensal rodent in most of the USA). While the EPA notes that first-generation products have passed efficacy tests in the laboratory, registration data based upon albino rats and mice or susceptible strains do not reflect wild populations. Evidence suggests renewed field use could even reduce efficacy with some of the less toxic second-generation anticoagulants as has happened in parts of Europe where brodifacoum has not been widely available.

There seems little cause for and considerable concern about reclassifying the second-generation products for restricted use and thereby removing them from use by consumers who live in the urban environment and who are most at risk from these harmful rodents. Yet there is every reason to conclude that returning to control practices of the 1960s and 1970s will have the same impact as demonstrated and documented during that era. Doing so would undoubtedly have a negative impact on public health and cause consumers to use greater quantities of less effective rodenticides. This outcome, coupled with declining urban conditions in the U.S. predictably will result in increasing problems with pest rodents. Residents of cities in 21st century America will likely find throwback conditions without the tools or expertise they require to make effective headway in reducing rodent problems.

1.3 Comparison of Efficacy of First-Generation Anticoagulants and Acute Rodenticides With the Second-Generation Anticoagulant Products

First-generation anticoagulant rodenticide products have serious limitations when compared to the second-generation anticoagulant products. The superior efficacy of brodifacoum, for example, has been documented throughout the world (Kaukeinen & Rampaud, 1986). Specifically, the first-generation rodenticides are multiple feed products, requiring an excess of bait to be maintained over several days and also requiring that rodents repeatedly return to feed at the same source. Having to use more bait for first-generation products when compared to second-generation products, increases the risk to non-target animals while reducing control of pest rodents that often feed sporadically. Lack of control, because of genetic resistance or sporadic feeding, further increases the potential for people to apply and prolong use of greater quantities of first-generation anticoagulant bait.

House mice are particularly common in residential settings and the most abundant pest rodent in the U.S. In a review of available published data, John Greaves (1985) questioned the suitability of warfarin as a rodenticide against eight species of rodents, including the roof rat and the house mouse. House mice have a naturally low susceptibility to not only warfarin, but to other first-generation anticoagulants as well, such as diphacinone (Prescott, 1996).

Warfarin products are typically formulated for use at a 250 ppm concentration, which is five to ten times more concentrated than second-generation anticoagulant baits. Although chlorophacinone and diphacinone baits available to consumers today are at 50 ppm concentration, the National Wildlife Research Center found it necessary to use 100 ppm chlorophacinone and diphacinone baits to achieve efficacy in 15-day tests with house mice (McCann, 2000), even though the EPA in its Rodenticide Cluster RED document determined

that concentrations of these products for field (agricultural) bait uses over 50 ppm should be ineligible for reregistration (Silberhorn, et al, 2000). Some manufacturers of commensal baits may seek to raise the concentration of these older materials if they are to be made into competitive products in a consumer market used to the efficacy of second-generation products, or may seek to add drugs or other synergists with unknown environmental and non-target impact (e.g., Poche, 1998).

Toxicity comparisons between first- and second-generation anticoagulants as cited by the EPA and others typically use acute oral LD50s derived from intubation of dilutions of active ingredients, whether with target rodent species or in the lab with non-target animals. Such comparisons result in estimates that the second-generation products are perhaps 100 times greater than first-generation products. However, valid comparisons of the true toxicity of anticoagulant rodenticides must be considered by comparing daily divided doses, using the same mode of action required for first-generation products. Making a comparison of daily 5-day daily oral LD50s with rats and mice, for example, the difference in toxic amounts is much less. Determinations with house mice indicated values for warfarin of 2.20 mg/kg vs. diphacinone at 1.41 mg/kg vs. chlorophacinone 1.19 mg/kg vs. bromadiolone 0.15 mg/kg. For wild rats, daily 5-day values for warfarin were 0.44 mg/kg vs. 0.16 mg/kg for chlorophacinone vs. 0.07 mg/kg for bromadiolone for wild rats (Ashton, Jackson & Peters, 1986). Therefore, the true difference in toxicity between first- and second-generation products is an order of magnitude less when comparing 5-day divided doses reflecting multiple exposures, versus acute oral LD50 values.

First-generation, multiple feed anticoagulants have been registered based upon different efficacy requirements than those for the second-generation anticoagulant rodenticides. The older materials, such as warfarin, chlorophacinone and diphacinone, typically are tested using protocols exposing the test animals to 15 to 21 days of feeding and such methods require minimum palatability figures in addition to mortality minimums. This excessive exposure and resulting mortality in the laboratory gives a misleading impression of efficacy for such products when compared to what should reasonably be expected in field use, where rodent consumption of baits is limited and sporadic.

Additionally, these older products continue to benefit from the maintenance of 'conditional' registrations, whereas the more modern products such as second-generation anticoagulants, have had both extensive initial data requirements as well as subsequent data 'call-ins' (Jacobs, 1992). Unlike the first-generation anticoagulant products, the second-generation products do not require a minimum palatability figure because they kill in a single feeding, so the only relevant criteria is sufficient mortality of the test group. Switching to first-generation products will likely result in products being developed and marketed with sweeteners, flavorings and scents that are added in an attempt to increase rodent palatability to meet the criteria, but which could well increase risk to children, pets and wildlife as well. Such products may perform well in lab efficacy trials (usually with albino rats and mice), but there is no guarantee that wild rodent infestations will find the products attractive or feed sufficiently upon them to ingest the necessary dose over several days. Consumers may experience a lack of efficacy with the addition of attractants such as peanut butter or candy to the entrances of stations – increasing risk to children and pets.

The EPA has proposed that acutely toxicity rodenticide products could be used in place of, or used in rotation with, anticoagulant rodenticides, to avoid the development of anticoagulant

resistance. The drawbacks of acute products include lack of an antidote, development of bait shyness, and hazards to non-target animals (especially pets). Acute rodenticides are more rapid acting and with profound effects on body systems that lead to such outcomes as paralysis, heart failure, and kidney failure before death. Anticoagulants have been studied in rats through monitoring of nervous system responses, and clinical signs of pain or distress from delayed internal hemorrhage, the primary cause of death, were not shown. Conversely, tests with products causing acute symptoms and paralysis were judged inhumane (Corrigan 2001).

Faster acting acute rodenticides typically produce bait shyness (feeding avoidance) in sublethally poisoned rodents. This phenomenon has been noted for cholecalciferol (Prescott, El-Amin and Smith, 1992) and zinc phosphide (Marsh, 1987). Studies have noted that control of wild rat populations with high degrees of anticoagulant resistance was not effective with use of calciferol and zinc phosphide non-anticoagulant materials (Quy, MacNicoll & Cowan, 1998). Further, these researchers note that the restriction of brodifacoum in the UK prevented effective use of this product to control rats resistant to warfarin and other anticoagulants.

Many authors recommend pre-baiting with acute products, to overcome intrinsic lack of palatability and bait shyness (Hadler & Buckle, 1992). Prebaiting complicates and lengthens time to control with acute products. Currently no commercial acute rodenticidal product is available with, or is recommended as using, a prebaiting (placebo) formulation prior to application of the toxic version. Prefilled stations would make such approaches more difficult, increasing or sustaining efficacy limitations of available acute products. Feeding rats and mice, before killing them, is not a requirement for effective control with anticoagulant rodenticides. Bromethalin and calciferol have been withdrawn from the whole of the European Union effective September 2006, because of a lack of data as required by the European Biocides Products Directive (Buckle, Sharples & Prescott, 2005).

2.0 Non-Target Animals – Background

The registrants of second-generation anticoagulant rodenticides have provided a robust data set and considerably more information on their products than was provided to EPA in support of earlier rodenticides. Thus, for second-generation products, submitted studies included those concerning mode of action, therapy and antidoting, handling and disposal, basic toxicity screening on a number of indicator animal species, environmental fate (microbial action, soil mobility and dissipation) and wildlife hazard studies (Kaukeinen, 1982). The lack of such detailed information for first-generation anticoagulants should not be taken to mean that they have less intrinsic hazards or cause for concern.

All rodenticides are vertebrate toxicants, and none of the currently-available products is completely specific to rodents. Consequently, non-target animals that potentially might be exposed to rodenticides include people, domestic animals, and wildlife – particularly birds and mammals. Rodenticide selectivity is developed through the use of formulations that are specifically and demonstrably palatable to the target pest rodent, and by making careful placements in areas most likely to be frequented by the target species. Use of small quantities, protected placements, human taste deterrents and other techniques have been developed to reduce hazard under normal, labeled use patterns.

While non-target animals can develop poison symptoms when fed rodenticide formulations under laboratory conditions, this is not useful in predicting and in assessing hazard in actual use. The opportunity for exposure to people, pets and domestic animals is controlled by how and where these products are used. Thus, to assess the potential risk to some wildlife species, such as seed-eating birds, from direct consumption of rodenticide bait the Agency should consider that commensal rodenticide products are not likely to contribute to such exposures because they are not labeled for outside broadcast use. It is remotely possible that wildlife bird and mammal predators and scavengers could conceivably ingest the rodenticide from eating poisoned rodent prey. Yet for these species, lab data demonstrating some level of susceptibility bears little relationship to ecological vulnerability in the wild. Similarly, the concentration of recovered residue in an animal does not necessarily relate to mortality or degree of exposure, and the presence of residue does not provide any evidence that exposure was related to use of consumer branded products (Kaukeinen, Spragins & Hobson, 2000).

Field hazard studies are needed to determine the likelihood of wildlife exposure under conditions of actual use. Since consumer use of commensal rodenticides are labeled specifically for use in and around structures, the potential for wildlife contamination (especially due to predation upon target commensal species) is extremely limited. Moreover, to the extent that consumer product uses, or uses by professional applicators, may have the potential to contribute to such exposures, label instruction statements could be adjusted to explain best practices to avoid such inadvertent exposures.

2.1 Comparisons in Antidotal Treatment of Rodenticide Poisoning

All anticoagulant rodenticides share the same mode of action, blocking the epoxide reductase enzyme in the liver, and there is no significant difference in time to death once the enzyme is blocked and internal vitamin K action is stopped, leading to hemorrhage (Hadler & Buckle, 1992). The incidence of actual accidental poisonings (as distinguished from exposures or contacts) in humans is extraordinarily limited -- and a recent review of reports and the literature confirms that treatments for mere exposure and contact do not require hospitalization or antidote therapy. Nevertheless, the treatment of poisoning is also common to all anticoagulant rodenticides. The availability of an antidote, vitamin K, is unique among pesticides in general and to rodenticides in particular -- most poisons do not have an antidote that completely reverses harmful effects. Vitamin K has proven to be an effective antidote for all anticoagulants that have been developed, including the second-generation anticoagulant products. In those rare occurrences involving deliberate ingestions and poisonings, different anticoagulants may require different treatment periods, although the only significance in clinical treatment is typically as between warfarin and the rest of the anticoagulants. Warfarin can be eliminated from the body in hours, whereas other first-generation anticoagulants, and the second-generation varieties, can take weeks (Hadler & Buckle, 1992). The treatment for all non-warfarin anticoagulant rodenticides is extended, e.g., for diphacinone (Mount & Feldman, 1983) requiring daily divided doses.

None of the available non-anticoagulant rodenticides have an antidote. Bromethalin causes a depletion of energy in the cells of animals ingesting it, leading to fluid buildup, paralysis and death (Dunayer, 2003). It has no specific antidote. Cholecalciferol disrupts the use of calcium in the body, leading to kidney failure and death, and has no antidote (Corrigan, 2001). Likewise,

the older acute product zinc phosphide has no antidote (Marsh, 1987). Any reasonable assessment of the risks and benefits of rodenticide products must take into account that there is a readily available antidote (vitamin K) for the anticoagulant rodenticides, including the second-generation products.

2.2 Wildlife Contamination Cases in Perspective

Information concerning wildlife exposures reviewed by EPA does not provide a sufficient basis to reclassify all second-generation products for restricted use as there is no indication that such products contribute materially to wildlife exposures. Specifically, low-level tissue residues of anticoagulants may reflect exposures of individual animals by unknown means, but such low levels may have no demonstrated deleterious effects. A review of available information resulted in a proposed 'threshold' value of concern – a level that has seldom been reached in wildlife cases to date (Kaukeinen, Spragins & Hobson, 2000).

The Agency has made reference in its proposed mitigation measures to surveys of wildlife exposures attributed to rodenticide use, yet the available information is limited to small samples from only a few geographic areas (inner-city areas were not represented) and which are not representative of the broader use of rodenticide products. Stone (1999) postulates a hazard scenario based on 55 carcasses analyzed for anticoagulants between 1971 and 1997 -- a recovery rate average of 2 samples per year, which include squirrels, chipmunks, raccoons and other common animals.

A California study (Hosea, 2000) gave results from 74 carcasses collected 1994-1999 that were analyzed for anticoagulant residues. Low-level (< 1 ppm) anticoagulant residues were found in 43 mammal samples and none in 13. First-generation anticoagulants were found in 9 samples, and second-generation anticoagulants in 34 samples (12 samples had multiple compounds). In tests with 41 bird samples, 31 had low-level residues (< 0.1 pm) and 10 did not. First-generation anticoagulants were found in 3 birds and second-generation anticoagulants in 28 samples (5 with multiple compounds). Route of ingestion and cause of death could not be determined in most of the animals, but greater concern was given to the anticoagulant recovered most often – brodifacoum.

The results of such studies must be reviewed and considered critically because the methodology for analyses of brodifacoum was 100 times more sensitive than that used for diphacinone or chlorophacinone, and 10 times more sensitive than methods used for bromadiolone at one lab, providing for more positive brodifacoum recoveries in relation to other compounds (Hosea, 2000). Similarly, at another lab used for some of the author's findings on California samples, methods for brodifacoum detection was 5 times more sensitive than that for bromadiolone and 25 times more sensitive than that for difethialone, diphacinone and chlorophacinone, again providing the opportunity for considerable bias that undoubtedly contributed to the findings. In addition, first-generation anticoagulants are metabolized more rapidly, so affected animals may show less residue burden in comparison to the longer-lasting anticoagulants. Low sample numbers, unequal analytical sensitivity, differential metabolism, and unknown effects of very low residues do not seem to provide for meaningful conclusions. The fact that this study found examples of both first- and second-generation anticoagulants in this small sample suggests that some wildlife exposures (whether from labeled or off-label use) will occur regardless of what

anticoagulant product is available in the marketplace. However, the study does not provide a sufficient basis to reclassify consumer use products for restricted use.

Moreover, the findings of small quantities of anticoagulant residues cannot generally be equated to adverse health effects, particularly at the low levels observed. For example, a group of 10 apparently healthy coyotes from California were euthanized and levels of bromadiolone and brodifacoum from 0.07 to 0.46 ppm found, although the necropsy showed no symptoms consistent with anticoagulant toxicosis (Kaukeinen, Spragins & Hobson, 2000).

The New York sample data (Stone, 1999) includes recoveries of coumatetryl anticoagulant, which is not sold in the USA. This finding calls into question the analytical techniques and standards used by that lab. If the findings were not in error, then the conclusion drawn is of illegal importation and use of an unregistered product from another country. Restricting the use of US-labeled products will hardly impact such misuse -- and might increase it.

Stone (1999) lists 7 white-tailed deer as having anticoagulant residues, which clearly involve off-label use. Product misuse which contributes to wildlife exposure will not be discouraged by product reclassification. A subsequent paper (Stone, Okoniewski & Stedelin, 2003) concerns raptor analyses between 1998 and 2001 as collected in conjunction with West Nile Virus surveys. Anticoagulant residues were detected in 49% of 265 samples, although anticoagulants were considered the cause of death in only 7% (9 cases). Warfarin, chlorophacinone, and diphacinone were recovered in addition to bromadiolone and brodifacoum. The greater recovery of second-generation anticoagulants is likely due to greater (more sensitive) limits of detection and larger volume of those products in use.

Simply linking the finding of rodenticide residue to product risk is inappropriate and misleading. In actuality, observations of wildlife exposures to specific active ingredients reflect the comparative market share of various rodenticides (Kaukeinen, Spragins & Hobson, 2000). A survey cited from 1998 notes that over 98% of professional applicators were using second-generation anticoagulant products as their primary tools against commensal rodents, and that percentage is expected to be comparable in the retail market where versions of similar products are available. Over 40 million retail product placements of second-generation anticoagulants were calculated as being made by consumers yearly in the late 1990s, compared with less than 2 million placements of first-generation products, so reports reflecting product misuse would be expected to have greater association with the second-generation type products, based on the quantities sold. So, when adjusted for sales volumes, there is not a disproportionate relationship in reports of non-target incidents between first-generation and second-generation products.

The total number of reported 'wildlife incidents' from New York and California ranged between 6 to 19 cases yearly in these states during the years 1996 and 1997, while the total pounds of formulated rodenticide product (all types) sold in those two states ranged between 3 to 9 million pounds in those years (Kaukeinen, Spragins & Hobson, 2000). Thus, the reported wildlife exposure rate for rodenticides is very low in proportion to the amount used. After registration and decades of effective use of these products, EPA has not established that there can be a finding of 'unreasonable adverse effects' when the evidence of wildlife exposure is considered in light of the obvious public health and economic benefits and need for such.

An extensive review by USDA of pesticide incident reporting systems in place in California found that the number of adverse pesticide exposures, involving either humans or wildlife, is insignificant in comparison to the total number of reports and the amount of pesticide used (Dewey & Bergman, 2000). Examination of data from other states, including Washington, and the AAPCC human case data also showed that reports of adverse effects were minimal. Dewey and Bergman (2000) found that the few adverse products for FIFRA 6(a)(2) purposes, upon investigation, were most often caused by accidental misuse or intentional abuse of a pesticide product.

2.3 Risk to Companion Animals from Alternatives to Second-Generation Anticoagulant Rodenticides

The majority of publications describing secondary intoxication of animals from anticoagulant rodenticides that are frequently cited appear limited to unique overseas use patterns (or experimental testing of non-registered products) involving broadcast baits and various wildlife species and situations not present in the U.S. Reports in the U.S. of secondary poisoning to pets from second-generation anticoagulants do not figure in the veterinary literature (Murphy & Gerken, 1986; Corrigan, 2001), yet dogs and cats represent a far more likely scenario in being exposed to poisoned commensal rodents than wildlife. The toxicity of second-generation anticoagulants to dogs has been reported (based, in some cases, on studies with as few as 6 animals), but the most robust study puts brodifacoum as comparable in toxicity (LD50 of 3.56 mg/kg) to the other second-generation products with regard to canines (Godfrey, Reid & McAllum, 1981). Diphacinone, a first-generation rodenticide which would not be restricted under the EPA's proposal, is more toxic to dogs than the second-generation anticoagulants, and cats and dogs are highly susceptible to the effects of the acute rodenticide cholecalciferol (Corrigan, 2001).

Bromethalin, an acute rodenticide that would not be restricted under the EPA proposal, is highly toxic to dogs - - between 2.4 – 5.6 mg/kg, and cats are even more sensitive (Dunayer, 2003). Reports by the National Animal Poison Center of the Humane Society of the U.S. note that bromethalin is now the most common active ingredient involved in poisoning cases of household pets (Khan & Farbman 2006, 2007). This potential for adverse impact to household pets is expected to increase if wider use of bromethalin products is made in the home with the loss of second-generation anticoagulant products, as proposed by EPA.

2.4 Environmental and Hazard Impacts of Consumer Use

Individual homeowners usually have limited capacity to alter community conditions that broadly sustain rodent infestations in neighborhoods. Most homeowners only take action when rodents invade their homes. Thus, the home represents the point at which the most effective control methods must be encouraged and preserved. The most effective means of rodent control must, therefore, remain available for consumers. Municipal programs rarely enter residences or place rodenticides inside private properties, and most municipal programs are not able or funded to stem neighborhood problems producing rodents that colonize residences. Additionally, inner-city residents typically do not have the ability to pay for effective and professional services for pest rodent management.

Rats and mice can exist throughout a structure where they move about through structural voids, utility chases, and similar systems that interconnect floors and buildings. Similarly, rodents readily shift in and out of urban structures using underground utility systems and voids. Interconnected populations produce persistent infestations in urban buildings and require effective control techniques where it is possible to place such materials, since total access to these interconnected populations is not often possible. Thus, use of a single-dose rodenticide is the best choice in areas where rodents have other available food and are dispersed within urban infrastructure. Both rats and mice are secretive and hoard food in their burrows and nests, and they feed in secluded spots. They are unlikely to return to rodenticide bait to re-feed if they have alternatives and are moving throughout a building's remote infrastructure. Second-generation products that are 'single feeding' are more suitable than any other products when attempting to control these secretive, mobile and sporadic feeding pests that are increasingly becoming the primary rodent problem nationally.

The EPA's proposals do not limit consumer baiting to indoor use only, although doing so would more effectively limit the opportunity for wildlife exposures as compared to restricting the use of second-generation products to use by certified applicators. In fact, many consumer products are already labeled for indoor use only (and, packaging and use instructions for those products are inappropriate for outdoor use in any case). EPA has not carefully considered alternative, and less restrictive, methods for ensuring that products labeled for consumer use do not inadvertently lead to exposures to non-target organisms. Limitations, such as an "indoor use" instruction, could easily be added to consumer products (Silberhourn et al, 2000).

2.5 Risk to Wildlife from Alternatives to Second-Generation Anticoagulant Rodenticides

The EPA has recognized the advantages of second-generation products in terms of efficacy for the user. These products provide control of target rodents as the result of a single night's feeding, which was an efficacy trade-off compared with the first-generation products that were less likely to affect any animal (target or non-target) as a result of one feeding (Jacobs, 2000). It seems inappropriate to reclassify second-generation products without considering alternatives and the possibility that use will increase of other products with different modes of action and efficacy and potentially greater hazards.

Acute rodenticide products to be unaffected by the proposed mitigation decision are capable of presenting a hazard to domestic animals and wildlife (including non-target animals) in terms of direct (primary) poisoning. Bromethalin and cholecalciferol possess considerable toxicity to canine and feline species, and the older product zinc phosphide is generally hazardous to a variety of wildlife. The potential for misuse of the acute products by a person against wildlife is as great for these products as it is for second-generation products.

Only the second-generation anticoagulant rodenticides have been subject to extensive field studies to evaluate non-target hazards, such as to assess secondary hazard to wildlife (Colvin, 1984; Hegdal & Blaskiewicz, 1984). The evaluation of hazard is a complex undertaking (Colvin & Hegdal, 1988) but is necessary to determine population effects (which cannot be determined from laboratory studies). Use pattern (quantity and baiting location) is the major factor in managing the 'real world' risk (hazard) to non-target animals. The feeding behavior of non-

target wildlife (prey and habitat selection) is the deciding factor in hazard assessment, and not necessarily the rodenticide toxicity that can vary widely among species. The use of consumer products with second-generation active ingredients in homes and immediately next to buildings in populous urban and suburban areas has not been shown to expose wildlife to significant risk, and none of those products are labeled for agricultural use. Thus, there does not appear to be any basis in the published literature to support reclassification of the consumer use products to mitigate unsubstantiated concerns.

No adequate field evaluations have been conducted to examine the hazards to predators and scavengers from the use of first-generation anticoagulants. It can be expected that use of these products is not without risk to wildlife, particularly given their agricultural use pattern in some areas. The state with the largest number of wildlife cases with anticoagulant rodenticide recoveries (California) has significant use of first-generation products for agricultural rodent control in open areas (Timm, 2004). Over one million pounds of bait (including chlorophacinone and diphacinone formulations) have been used yearly since 2000 for controlling ground squirrels, voles and gophers. A tax on the bait was used to fund research on efficacy studies, but the non-target impact of these products in use was not evaluated (Timm, 2004).

There has been an increase in coyote-human contact in California, and attacks on humans are not unusual in many urban fringe areas, where coyotes may have lost their fear of people and may consider children and pets as prey (Baker & Timm, 1998). A total of 53 attacks on humans between 1988 and 1997 reveal that urban sprawl is increasing this phenomenon, and homeowners may take measures to control such wildlife for self-protection. This may certainly be a basis for incidents of anticoagulant residues found in coyotes in California and elsewhere. Similar surveys note conflicts between mountain lions and humans have greatly increased over the period 1972 to 1997 (Mansfield &Charlton, 1998). Increased interactions between humans and wildlife may lead some to take illegal measures, utilizing whatever rodenticides are available. There is no basis for EPA to conclude that removing second-generation consumer products from the market will in any way modify such behavior as any remaining products would certainly have the ability to cause harm if used irresponsibly.

2.6 Human Poisoning Risk from Rodenticides in Perspective

The American Association of Poison Control Centers publishes an annual report of calls received by participating public poison centers regarding potential exposures or poisonings. The latest publication (Lai et al, 2006) summarizes calls in 2005 and aggregates all calls to 61 reporting centers. Numbers in the annual report need careful study to ensure accurate interpretations. The AAPCC report clearly states that the number of 'exposures' they record to any toxicant does not necessarily represent a poisoning or an overdose.

In 2005, there were 2.4 million total exposure calls reported (Lai et al, 2006). Approximately one million calls were drug-related. Half of all such calls involved adults, including substance abuse and suicide attempts. Contacts with drugs constituted the bulk of incidents involving children less than 6 years of age, followed by ingestion of cosmetics and household cleaning products. Pesticide-related contacts accounted for 4% of child exposures, less than that for seven other categories including the above along with cough syrups and household plants. Of slightly more than 100,000 calls nation-wide concerning pesticides, only approximately 15,000

concerned anticoagulants. Of note, adverse effects were reported in only 290 (0.02%) individuals of all ages, exposed for all reasons combined, including unintentional or intentional exposures. The single fatality with long-lasting anticoagulants as reported in 2005 was an adult, involving intentional ingestion. Additionally, regarding all pediatric exposures represented in the database, phytonadione, also known as Vitamin K1 (the antidote for long or short acting anticoagulants of any kind) was reportedly used only 51 times in children less than 6 yrs, regardless of the indication.

In contrast, exposures to acute rodenticide products (bromethalin and zinc phosphide, in particular) resulted in treatments in a health care facility more than 30% of the time – and there were two human fatalities reported with bromethalin in 2005. The data in the 2005 poison center report demonstrates that few exposures to long acting anticoagulants result in either symptoms or need for antidote administration in the pediatric population. EPA proposed mitigation measures will not lead to a reduction in the number of cases involving actual hospitalization or serious treatments of children if the acute rodenticides without antidotes are relied upon.

3.0 Efficacy Implications of Alternative Products – Background

The EPA is incorrect in assuming that after placing restrictions on second-generation anticoagulant rodenticides there will still remain available rodenticides with equivalent efficacy. Older anticoagulants are less efficacious and require multiple feedings, and all U.S. post-rodent species have demonstrated genetic resistance. This is why second-generation products were developed and have largely replaced first-generation products in urban areas.

Additionally, acute rodenticides present a primary hazard to non-target animals, are less humane than anticoagulants, and do not have an antidote in the case of accidental poisoning. Limiting consumer rodenticides to wax blocks in bait stations will further reduce efficacy due to lessened palatability and rodent neophobia when entering stations. Traps and glue boards present their own associated hazards and limitations (including exposing users to bites and germs). Second-generation products continue to be the most effective and affordable alternative for responsible rodent control in and around where people live and are the best products that research and development, and success in the marketplace, have provided.

3.1 Wax Block Formulation Limitations

Wax block formulations are not reasonable replacements for consumer use products for a number of reasons. In terms of comparative efficacy, grains and seeds are natural foods for pest rodents, particularly for house mice. Baits simulating these materials (including pellets) are well accepted, if they contain high-quality ingredients. Mice and rats also will extend their food preferences to foods found in their environment, which may include birdseed, dog food, the snacks found in offices, etc. Thus, there is an advantage to maintaining a variety of rodenticide formulations on the market so that different formulations can be matched to particular needs. Rodent infestations develop because of an availability of food materials in the area – and wax block products (especially on their own) will not perform well when other food sources exist.

EPA has not considered the problems associated with the reduced palatability of block formulations. Wax-block baits were developed for use in outdoor, moist situations such as

sewers, drains and burrows and require from 20% to 40% wax to maintain sufficient weatherability and hold grain ingredients together. Putting weatherable wax sewer and drain-type bait inside of a protective bait station and inside of a structure is not a logical match of product to application. Wax has no intrinsic taste or palatability to pest rodents and acts to decrease their acceptance of such products. This requires the addition of sweeteners and flavorings to overcome this drawback. The EPA has recognized that block baits are less palatable and has reduced the efficacy standard for some wax block rodenticide products compared to other types of formulations, such as pellets or seed baits. While second-generation anticoagulant actives work reasonably well in wax-block baits, given their single-feed properties, the first-generation anticoagulants will perform poorly because the low palatability of wax block rodenticide formulations is likely to limit the refeedings needed for ingestion of a lethal dose.

The high wax content of block formulations complicates the addition of many formulation ingredients, as well as making analytical results (e.g., quality control) far more difficult in recovering active or deterrents from a wax matrix. These difficulties will limit the ability of manufacturers to develop wax block formulations to meet the EPA's proposed requirements. Most active rodenticide ingredients besides anticoagulants are not amenable to incorporation in wax formulations. These acute products may not be stable in the high-temperature processes that produce wax block products, and few block products have ever been marketed that contain zinc phosphide, cholecalciferol, or bromethalin. While human taste deterrents such as denatonium benzoate can be incorporated into wax blocks, the presence of wax in such formulations can impart a very different taste perception from deterrents in pellets or other non-wax formulations, since the deterrent is within a paraffin matrix yet must be in contact with moisture (as in the mouth) before the bitter taste is evident. The same can be said for the inclusion of sweeteners in attempts to improve rodent acceptability.

In terms of hazard reduction, the EPA's stated preference for wax blocks is based on the argument that they can be better held within protected placements (bait stations). Yet wax blocks present drawbacks in hazard management as well. Formulations of wax blocks that contain whole grain or portions of grain stimulate rats and mice to gnaw the block apart to consume the grain particles, leaving toxicant-containing particles loose in the bait placement that can fall out of stations and be exposed to non-target animals. There are no EPA requirements of manufacturers to avoid inclusion of whole grain particles in wax block formulations versus finely-ground grain ingredients that rodents cannot isolate and select. Paraffin formulations may also delay absorption of the active ingredient in the pest after bait ingestion, and allow more of the active ingredient to pass through the body and be excreted in feces, which could present a greater environmental risk.

The relative size difference of wax blocks versus other formulation types is also of concern. Wax block rodenticide products currently on the market are generally at least 20 grams (3/4 ounce) in size, versus pellets that can each be a fraction of a gram in weight. Relocation of a single block from the point of placement presents a far more serious exposure issue than a few pellets. A single block of some products might present a quantity of concern for accidental exposure when compared to the individual exposures that can be generated by a few pellets or other formulation types. Blocks more closely resemble candy and other food ingredients, and are much easier for a small child or pet to pick up and place in their mouth than a small pellet or bit of grain or meal bait. If bait stations with blocks are to be refilled by consumers, the block refills

will be unprotected from the point of purchase to home storage, to package opening, to being secured inside a proper station (assuming that consumers correctly maintain the security of the rodenticide throughout and apply it correctly to the protected placement).

Limiting consumer product formulations to only wax-block baits will reduce efficacy for those remaining products (first-generation anticoagulants and acute rodenticides) for which more consumption is required for a lethal dose. Wax block products were designed and intended for direct application to moist environments, e.g., in sewers, and they may be less effective for above-ground station use than other formulation types. Improvements in acceptability and hazard reduction with wax block formulations are harder to achieve, and they are not as efficacious as other types of formulations.

3.2 Consumer Bait Station Limitations

Pest rodents utilize in a three-dimensional environment and their home range and movement patterns cannot adequately be intercepted if baiting options are limited to the use of bait blocks within stations. Rodents are not always located within a structure in a location suitable for placing bait stations – which cannot easily be placed in areas such as inside walls, burrows, attics, and crawl spaces -- so isolated colonies cannot be reached unless small packages (e.g., place packs) are available. This means that chronic and unresolved rodent problems will persist in homes and spread through associated structures. When only selective harvesting (baiting) of a large rodent infestation occurs, because of inadequate control efforts, reproductive rates among survivors will increase given less competition for food; the subsequent result can be greater abundance of rodents and impacts than before the control efforts began.

As a result of the EPA proposed action, bait will be concentrated in bait stations in accessible floor-level locations, rather than commonly placed in isolated locations in wall voids, among utility ducts, in cabinets or behind appliances where the bait readily is fed upon by the pest rodents and commonly is less accessible to pets and children. Concentrating bait in a station and having bait stations within easy reach of people and pets in a home may pose more potential risk – in addition to the assured risk of direct exposures of building occupants including children and pets to rodents and rodent wastes because of poor bait placement with stations and reduced efficacy from rodent avoidance of stations.

Consumers have no experience in using rodenticide bait stations and will experience control limitations in attempting to use these new products. Station use will result in delayed control, which will be less acceptable when quick control is needed when rats and mice are inside a dwelling and posing a risk to residents. Rodents, especially rats, have behaviors (neophobia -- fear of new objects in a familiar place) that keep them from readily entering bait stations. Delays in entering stations by wild rats can extend to weeks, based on replicated studies (Kaukeinen, 1988) that concluded the extent of delay was related to the degree of tamper-resistant features such as inner baffles. Delays with mice are more related to placement than station design, with poor placement (in less active areas) causing significant delays (Morris and Kaukeinen, 1988).

The Norway rat is a burrowing animal, and normal infestations will have burrows (Jackson, 1982), a preferred baiting location. The loss by consumers of the ability to bait in rodent burrows can have serious drawbacks in achieving control; burrow baiting is one of the most

effective and safe methods for rat control. Work by Quy, et al (1996) noted that even less palatable rodenticide formulations could control local rat infestations if placed in burrows, while the same baits in above-ground containers were not readily consumed when alternate food was available. The authors concluded that the bait application method was the most important factor in whether or not a treatment was successful.

Bait stations will add substantial cost to homeowners -- having to purchase a complex plastic 'box' when only a small amount of bait is needed. Rodents may die inside stations, and homeowners will be exposed to rodent diseases by opening stations and servicing them. The stations themselves may constitute an 'attractive nuisance' item that children will want to investigate, since they will not be fastened down and cannot be as easily hidden because of their size and shape.

A significant increase in the cost of purchasing a small amount of bait (with a required bait station) will hamper consumer use of rodenticides. Consumers cannot be expected to purchase enough rodenticide bait placements, when costs are increased with the need for stations, and if the active ingredients require the use of more bait due to multiple-feed requirements. As a result, effective control will not be achieved. Rats commonly move 25 to 100 feet from their nests (Corrigan, 2001), and thus rat infestations in and around homes would require several stations to provide sufficient baiting points, even if suitable locations for such stations existed. The very limited home range of house mice would make careful and regular (many small) placements important. Consumers have little understanding of mouse territories, home ranges, and activity periods. Corrigan (2001) notes that research indicates the typical home range of mice in buildings is within 10 to 30 feet from the nest, and that this area becomes smaller as population size increases. The thigmotrophic and nocturnal behavioral patterns of mice lead them to restrict much of their movement to dark, hidden areas that may be difficult for station placements. Utility passageways commonly are used by mice within structures, including at high, hard to reach, and narrow locations that are not conducive to bait station placement. Thus the EPA proposed mitigation measures, requiring bait station use, put consumers in a position where they no longer can financially or physically match the distribution of mouse infestations within a structure or the methods needed to control mice.

Mixed infestations of rats and mice are often present in residential situations. The use of mouse-sized stations in a rat infestation will quickly lead rats to chew apart stations (including mouse stations) attempting to reach the bait. This rat damage will usually expose bait and lead to loss of tamper-resistant characteristics. Placement of rat-sized stations can allow both rats and mice to feed, but some rat-sized designs are not well accepted by mice (Corrigan and Collins, 2004).

The cost of bait stations for rats in the professional market is from about $7 to $15 each, in case quantities, sold without bait. It is expected that any consumer use stations sized for rats that are individually sold and filled with bait will sell for more than $20 each, making even one station prohibitively expensive to most consumer purchasers, especially in economically disadvantaged areas. In fact, the EPA (Jacobs, 2000) has already published an opinion that the tamper-resistant station option for consumers seemed less viable for rats than for mice. With the added cost of stations, homeowners would be expected to purchase and make fewer placements, resulting in persistent and growing infestations and risk in homes from selective harvesting.

Registration requirements for sales of prefilled stations in the consumer market will limit the availability of such products and contribute to cost increases. Tamper-resistant bait stations are commonly used by professional users, and are made by manufacturers in a variety of sizes and designs, principally in rigid plastic, but are sold empty (typically in case quantities with minimal packaging). Because prefilled stations require efficacy testing and registration (Jacobs, 1990), there are few examples of station designs suitable for consumers that have been validated for efficacy. Yet, the empty stations currently marketed to professionals may not be suitable for consumer use because they may not pass the efficacy tests to be required if sold prefilled. If prefilled stations are required for the consumer market, the testing and registration efforts by manufacturers will require a considerable time and expense, including necessary design development. Newer GLP testing requirements for rodenticides will cause increased delays and costs in new station product registrations (Poche, 1992).

Proper design of bait stations can be critical to their performance in controlling pest rodents. Mice have been shown to prefer larger stations (Volfova & Stejskai, 2003), but many retail manufacturers will undoubtedly feel compelled to keep mouse stations as small as possible to conserve "shelf space" (which is at a premium and competitively allocated in retail stores) and to reduce costs; this could further limit their effectiveness. Corrigan and Collins (2004) noted that a difference in height of stations could affect entry and feeding by mice by 15-18%. Such differences can be highly significant with multiple feeding baits and relevant to whether such products are efficacious when in stations. Station design also had an impact on the amount of insect attack on the bait, an important consideration when using stations outside.

The proposal for making bait stations required for consumer use includes keeping all tamper-resistant requirements as previously published, except for securing them in place. This exception to EPA's prior criteria (and one still required of professional users) renders even tamper-resistant designs of limited value in protecting bait. Children and pets can easily manipulate and kick loose stations that they may encounter, and attempt to open them. Plastic splinters from stations could be extremely dangerous to dogs attempting to bite or chew them. The utensils common in kitchens (a favored consumer placement location) could allow older children to break into these interesting boxes without much effort, since they could readily carry the stations to other areas of the home to play with or attempt to open.

Consumers are not expected to have experience in servicing stations, even if they place them correctly (in optimum protected active areas). Professional users of bait stations normally have policies of changing out bait on a monthly basis to keep it fresh and to remove moldy or decayed baits. Stations have locking mechanisms and require special keys to open. The EPA proposal contains ambiguity but seems to propose that consumer stations may be sold with additional bait block, yet to allow for refilling (which necessitates a 'refill pack' that is not sold in a protective station). There is no information that establishes that consumers can successfully place, bait, inspect, monitor, clean and service these stations as needed to ensure they are effective in use. If stations can be opened for refilling, then bait at that placement point can become contaminated, infested with arthropods, or become exposed to non-targets if care is not taken.

There is nothing to prevent consumers from removing bait from stations (or using refill blocks) and placing unprotected bait in other locations in an attempt to deal with a larger infestation when they cannot afford to purchase multiple stations (or if quicker control is desired without

waiting for rodents to enter stations). If the proposed consumer stations cannot be opened, then there will be limited ability to assess the condition of the bait or need for replacement of the unit. Further, consumers will not be able to remove dead rodents that die inside the station and will be forced to throw away a station that, with a refillable option, could be recycled for further use to limit consumer costs. One outcome of station use by consumers would be disposal of stations containing toxicant, adding non-degradable plastic and pesticide to the refuse stream.

Roof rats are common pests in the Gulf States and the West Coast of the U.S. Their attraction to attics and overhead areas make them particularly troublesome in buildings in these areas. Corrigan (2001) notes that when baiting roof rats in homes, interior baiting is not recommended, and that outside, baits often need to be placed in overhead areas. The proposed changes to homeowner products in use of bait stations would not seem to allow consumers to achieve effective control of roof rats with baits.

There is no EPA requirement for limiting station use to indoor-only situations. Placement of stations outdoors will render them susceptible to precipitation which can damage the bait, cause potential for vandalism when not well placed (hidden) or fastened down, or attack by non-target animals, such as dogs and squirrels, leading to potential for non-target exposure.

It should be noted that the stakeholder group assembled by the EPA in 1999 to review issues including mandating use of bait stations found that the stakeholders rejected the requirement that all products be sold in tamper-resistant bait stations (Silberhorn et al, 2000). The stakeholders group consisted of 25 members including governmental agencies including the Centers for Disease Control, the Consumer Product Safety Commission, and others.

Manufacturers have tried to introduce stations voluntarily to the U.S. market in the past, and none have met with consumer acceptance (American Cyanamid Combat station, Sherman Tackle station, d-CON mouse-killing station) that allowed for sustained sales (Kaukeinen, 1994; Jacobs, 2000).

To summarize, mandating the use of bait stations with wax block baits for consumers will limit their ability to control rodents due to: 1) the difficulty in finding suitable bait locations because of placement limitations; 2) delays of rodents entering stations; 3) incorporation of less effective rodenticide products; and 4) added costs of stations leading to inadequate use. Hazard will not necessarily be reduced, but could increase from the creation of new station products presenting a novel 'box' in the home environment, subject to investigation (and toxicant exposure) by children and pets. Delays to rodent control from limiting consumers to only bait station use also will increase the risk of economic damage and injury to people from pest rodents in their homes.

Better alternatives would be to continue to permit consumers to use second-generation products in small placements of packaged bait that can be better placed and hidden in active rodent areas and to enhance and clarify label precautions concerning where and how to bait responsibly. Addition of a human taste deterrent also would help reduce risk to people. These alternative actions would allow consumers to sustain the ability to control rodents effectively.

3.3 Non-Chemical Rodent Control Alternatives

Non-chemical control options principally consist of various types of traps. Mechanical traps and glue traps vary greatly in their effectiveness and utility, and there are no regulations or labeling protecting consumers from ineffective brands or guiding them in trap use. Outdoor use of traps can be problematic, due to the hazard to non-target animals (e.g., birds) and environmental disturbances that may render traps ineffective. Rat snap traps can pose serious injury to children, and even mouse snap traps can be traumatic if triggered by young fingers. Live traps require exposure of people to live wild rodents (with their diseases and parasites) and complicate disposal of the pest. Relocation (release) of harmful pest rodents by live-trapping cannot be recommended on any responsible basis, since it does not limit the hazard of rodents to people and other animals, but simply transfers the risk to others.

In using traps as an alternative to baits for homeowners, there is currently no labeling required to help ensure effective use and no minimum requirements for purchase. Users will experience moderate success but only if they follow correct placement, baiting and trap servicing. Corrigan (2001) recommends use of a dozen traps to control a pair of mice in a home. Few consumers are expected to buy this many traps. Placement and servicing of traps would be difficult for homeowners in suspended ceilings, burrows, wall voids, etc. as well as removing live or injured rodents. The removal of injured or dead rodents from traps by consumers and the proper disposal of rodents present concerns.

Increased trap use by homeowners from fewer bait products being available could increase hazards. Trap baits may include peanut butter, bacon, chocolate, and other attractive food that will present hazards to children and pets. Rat traps have considerable power and can be injurious to children. A considerable biohazard exists from trapped rodents. Handling traps will expose users to disease and parasites (rodent fleas, ticks and mites, plus endoparasites). Pets eating trapped rodents will likewise be at risk from bites (if the rodent is not dead) and from intestinal parasites and other rodent-borne pathogens. Traps are not discriminatory and their use outside may catch protected and desirable animals, including small birds, shrews, chipmunks, lizards and other animals that may be common around building perimeters and associated landscaping.

Trap shyness in rodents is common to glue traps and mechanical traps. Mice may take several days to investigate new objects in their territories and some will never interact with a trap at all (Corrigan, 2004). Rats and mice will remember near misses or injuries from traps, sticky surfaces and adhesive odors, causing repellency in further use (Corrigan, 2001). Glue traps are commonly rendered ineffective with mice in a few days from dust and dirt, and are not effective for rats (Corrigan, 2001). Mechanical traps are not easily placed or set in narrow areas such as cracks, burrows, or voids, where bait could be easily placed.

Trapping mammals is difficult, as professional trappers can attest. Rodents often elude capture, and once disturbed by a snapped trap or partial capture in a glue board may avoid such devices in the future. Commercial traps of different types vary greatly in their effectiveness. Corrigan (1998) evaluated glue traps to control field infestations of house mice. He found that snap traps were about seven times more effective than glue traps in capturing mice, and that enclosing glue traps reduced their efficacy even further. The author cautioned users against relying solely on

glue traps for effective mouse control. Glue traps remain of limited utility because some users will have concerns regarding humaneness (Frantz and Padula, 1983).

Ultrasonic and electromagnetic devices are sold to consumers and others with rodent problems, but testing has indicated they are ineffective (Howard & Marsh, 1985). There are no rodent chemosterilants that are commercially available, and sterile rats can still cause property damage and bite children. The polygamous nature of rat populations means that low numbers of fertile males and females can still maintain significant population levels, and thus proposals to use chemosterilants for urban rodent control are unrealistic.

Traps, the most common non-chemical alternative to rodenticides, can be an effective part of rodent control but pose problems in their use by consumers. They cannot be considered as an adequate option without the availability of other techniques to control or complete the eradication of most residential rodent infestations. Trapped rodent carcasses present a biohazard in terms of disease pathogens and internal and external parasites (ticks, mites, fleas). This risk (including attraction to dead rodents by harmful arthropod pests) is present from the time of immobilization in the trap (such as inside a home) until the carcasses can be removed from the premises. An advantage of slow-acting rodenticide baits is that rodents typically die away from the point of bait placement and in burrows or secluded locations. Rodenticide baits do not have to be set or positioned as with traps, nor checked daily for servicing or captured rodents. The use of traps with ineffective baits cannot achieve a level of control equivalent to the use of effective rodenticides, such as the second-generation anticoagulant products.

4.0 Alternatives to Proposed Actions - Background

The EPA proposed mitigation does not include appropriate alternatives and mitigation measures. The process of selecting mitigation measures should be inclusive of all known and logical alternatives, rather than proposing a narrow set of mitigation measures that clearly will not achieve reduced risks to the public either from rodenticides or rodents. The process of evaluating alternatives should consider both the risks and benefits of each alternative taking into account the impacts that pest rodents cause and the historic events and research that has led to the current technical approaches to modern day rodent control. The proposed alternatives will increase public risk and revert rodent control in the U.S. to that of the 1960s. These are not appropriate choices for numerous reasons and will not achieve the intended results of reducing potential risks to the public and non-target risks.

4.1 Use of Human Taste Deterrents and Dyes

The proposed EPA mitigation measures do not include steps that manufacturers have voluntarily taken to reduce potential hazards of rodenticides to children through the use of taste deterrents, even though the EPA has been directed by the Courts to reconsider the use of additives including taste deterrents and dyes. It should be noted that the stakeholders work-group assembled by EPA in 1999 to review rodenticide issues, including the addition of taste deterrents, recommended that any product reformulation include a bittering agent should be done at the registrant's option (Silberhorn et al, 2000). The stakeholders group consisted of 25 members from state, local and federal governmental agencies including the Centers for Disease Control, the Consumer Product Safety Commission, and others.

Considerable research (Kaukeinen & Buckle, 1992) documented aversion to placebo baits containing denatonium benzoate (Bitrex®) with human volunteers, and the maintenance of good efficacy to the target rodent pests in the lab and field. Consequently, some manufacturers voluntarily added this taste deterrent to one or more products.

Although the EPA has recognized the potential for the addition of taste deterrents since at least 1990, they have not required use of these additives by manufacturers (Jacobs, 2000) and the Agency has not adjusted its data requirements to enable willing manufacturers to succeed with this improvement. Further, the EPA has not allowed manufacturers who chose to add taste deterrents to make any statements on the label that would cause consumers to select for products with this additive.

Several rodenticide manufacturers have registered products containing bitrex, with the additional effort and expense of conducting and submitting efficacy data verifying continued product performance with pest rodents. It is curious that in the instance of human taste deterrents, the EPA seems to discourage their use while maximizing product efficacy, rather than accept some potential loss of efficacy if doing so would reduce risk to children.

The EPA has not discussed in its proposal the use of dye products with warning colors; yet some current products are sold in a natural brown or grain color consistent with the appearance of some energy bars or candy. A number of dyes or pigments are available to color pellets, blocks, or other current formulations. These colorants are generally water-fast and do not rub off, but uniquely colored rodenticides could be distinguished from food and candy materials.

A visible 'indicator dye', also championed by some consumer advocates, is generally taken to mean a material in or on rodenticide baits that, if touched, would mark the child (such as on the hand or mouth), alerting parents to a possible bait exposure. Many have voiced limitations with this approach, but the concept remains a valid area for further research. To succeed, such dye would have to have no oral or dermal toxicity, nor provide a lasting stain to the skin or finished surfaces. While this option might not reduce the number of true exposure incidents, it might give physicians additional evidence to determine if treatment was necessary.

Alternatives, such as these, deserve more careful consideration and should have been evaluated by the EPA in a risk-benefit analysis.

4.2 Additional Restrictions in Use Areas for All Products

Most commensal rodenticide labels (for both consumer and professional products) currently contain a number of precautionary statements, such as: "Caution – may be harmful or fatal if swallowed", "This product is toxic to birds, fish and wildlife", "This product can pose a secondary hazard to birds of prey and mammals", "It is a violation of Federal law to use this product in a manner inconsistent with its labeling", "Do not expose children, pets or other non-target animals to rodenticides", "To help prevent accidents: Apply bait out of reach of ...non-target wildlife or in tamper-resistant bait stations", "Dispose of unused, spoiled and unconsumed bait", "For use in and around structures", "Do not apply in water", and "Do not broadcast bait". However, these statements do not preclude rodenticide use in many problematic areas. The

selection of treatment areas on most product labels is limited to a determination of areas where rodents will find and consume the bait in and around structures.

Rather than restricting some products from consumer users, EPA is obliged to first consider and evaluate the utility of adding further clarifications and specific use restrictions to existing rodenticide product labels. Such clarifications could preclude the use of all products and active ingredients in areas that could cause non-target exposures to certain species. Some of these possible statements for consumer products would include: "Do not apply in landscaped areas away from buildings where non-target animals may feed on the bait", "Not for use in parks and open areas or edge areas along such open areas", "Not for use in crops, gardens, around fruit or nut trees or decorative pools, ponds and fountains", "Do not bait outdoor compost piles", and "Do not use in areas around structures where hawks, owls or other predators are known or suspected to roost, nest or feed". "Do not use along fencelines bordering naturally vegetated areas." These restrictions would eliminate many problem areas where use of rodenticides could cause wildlife exposure, without reducing the ability of consumers to bait in and immediately against structures where pest rodents are known to be active.

Label restrictions could equally include products used by both consumer (homeowner) and professional users. Although the EPA mitigation proposals suggest that homeowners' application practices are the source of inadvertent exposures to non-target animals, there is no evidence in the literature to support this assumption. Professional pest control companies and municipalities make much more extensive and sustained (year round) outdoor placements of rodenticide around and near homes, commercial facilities, agricultural buildings, park structures, and other infrastructure. Thus, the EPA proposed actions would not necessarily reduce risk or current exposures from outdoor placements. Restrictions in use directions for all users and all products seem justified. Otherwise, incomplete efforts affecting one user group and one type of product will not eliminate other causes of potential exposure.

4.3 Possible Consumer Education Components

Rodenticide product labels are necessarily abbreviated to fit the size of product containers. Many consumers are capable of following updated and appropriate application instructions for the second-generation products. For example, misuse of other non-pesticide products has been constrained by limiting sales to adults, by a registry system, or sales after reading and signing that certain information has been reviewed and understood. Additional information could easily be provided as a point-of-sale feature (perhaps in voice-recorded chips, or with point-of-sale accessory information including short video clips, additional brochures, or interactive computer and product-dispenser displays).

Consumers are increasingly becoming more informed about the risks and benefits of pest rodent control in their homes and workplaces. Demands for rodent control are expected to increase, and thresholds for human tolerance of rodent presence and problems will lower. Written and broadcast media and Internet sources are already common information sources for urban residents.

Brochures, public service announcements, product labeling and literature, and internet sites could all focus public attention to those sources of information that offer valuable information on

recognizing and dealing with rodent problems. This effort could involve joint programs between the EPA, manufacturers and consumer groups working toward the effective and low-hazard use of all of the available rodent control methods and materials that are available. Aspects of those control approaches having specific concerns could be addressed, such as in the correct setting of traps or placement of rodenticides. Modules could be developed for general use by urban health departments and other city government groups that would give useful information on how to eliminate the risk from pest rodents.

The elimination of federal funding for urban rodent control programs, combined with limited municipal funding and expertise, has left a void in effective public understanding of the problem and effective control measures in urban areas. An integrated pest management (IPM) approach is needed, and IPM includes effective rodenticide use especially to resolve existing and immediate problems. The ultimate method for long-term rodent control is better environmental management and urban planning, and that also is the best practice for reducing overall rodenticide use and accomplishing risk management.

5.0 Anticipated Outcome if Proposed Measures Are Approved Without Modifications

The Agency's proposed risk mitigation measures, if approved as written, do not address many apparent and important aspects of user requirements and concerns, or solve problematic areas in rodenticide use. The measures would have negative impacts on the public (i.e. consumers, including the economically disadvantaged) who are most at risk from pest rodent injury, disease and property damage. With fewer rodent control solutions, and less effective methods, successful rodent pest elimination will be more difficult in the indoor urban locations where small amounts of appropriate rodenticide bait can be effective. A requirement for bait stations for consumers is unwieldy and eliminates many options for successful bait placement and further restricts effective rodent control. Station use will have no impact on the risk of secondary transfer of active ingredients to predators. The mitigation measures inappropriately single-out consumers (homeowners) as the source of wildlife risk, without considering product use by commercial applicators.

The proposed mitigation will have a negative effect on the registration of rodenticides. Vertebrate pesticides are a small market for manufacturers compared to many other categories of pesticidal products. Older anticoagulant and acute rodenticide actives retain no proprietary protection yet require comparable development and registration costs of newer actives. No new rodenticide actives have been registered since 1994 in the US, and hundreds of registrations have been lost. Jacobs (1992) documents 40 active ingredients for which some or all uses for vertebrate pest control were lost between 1983 and 1991. The requirement for GLP testing has increased costs for registrants from 40 to 200%, depending upon the type of test (Poche, 1992). Taken in concert, the increasing EPA requirements (both financial and scientific) to support vertebrate pesticides have acted to "kill" many such products (Jacobs, 1992). Change of labels to reflect a new restricted use status (in addition to loss of consumer versions of products) will place a burden on manufacturers who have supported the development and marketing of second-generation anticoagulant rodenticides to users.

First-generation anticoagulants have limitations in having multiple-feeding requirements, known genetic resistance that can render them ineffective and result in persistent rodent problems, and

still present risks to non-target animals that have not been characterized with adequate field evaluations. Acute rodenticide products possess non-target hazards and cannot be used repeatedly because of the development of bait shyness. Proposals that concentrate such products in and around the home in accessible areas (those amenable to the use of loose and visible bait stations) will increase the risk to children and pets.

The EPA proposals largely leave use pattern questions or problems unanswered, and allow professional users to continue their use practices unaffected (although the impact of professional users vs. consumers to non-target hazard risk has not been addressed). Anticipated outcome would revert rodent control to that in the 1960-1970 era, with reduced control, an increasing spread of genetic resistance in the U.S., greater use of rodenticide because of less control, and hazards from older anticoagulants and less selective acute rodenticide products. This would occur again in the urban areas where it was documented previously, and with declining resources of municipal authorities and rising costs of professional applicators, the residents themselves will have to take the primary role in being proactive in the use of rodent control materials.

At the same time, rodent problems in the U.S. are increasing as urban areas continue to age, neighborhoods become more congested, and areas with economically-disadvantaged residents increase. Thousands of acres of forest and open land are lost to development annually in the U.S., reducing habitat diversity and increasing the risk of rodent problems. With a warming global climate, rodent populations are expected to increase, leading to higher public health and economic risks from rodents. The elimination of effective products from the consumer market will leave rodents in contact with people in residential settings, and these rodents are not expected to be the subject of control efforts by municipal authorities or for-hire applicators.

The proposed risk mitigation measures cannot be expected to reduce the opportunity for non-target exposures, since no change is being made to professional use product labels governing restrictions in the use areas most vulnerable to wildlife exposure. These include those large commercial and agricultural accounts, parkland, and other properties where fence line and edge habitat is extensively baited. The maintenance of all available products subject to clear label limitations on use and with use-area restrictions would provide continued effective rodent control for all users, while allowing potential risks to be minimized.

It was over 35 years ago that the basic information on conducting successful urban rodent control was elucidated by David E. Davis and others (Davis, 1972). In the years since, technology has improved but many urban conditions have worsened, leading today's technical experts to recommend diverse IPM approaches within a carefully organized and strategic framework (Colvin & Jackson, 1999). Rodent pests in and around inhabited structures present a serious and growing threat, particularly in urban areas.

There are many preferred and better alternatives to EPA's proposed mitigation measures. Those alternatives can help manage non-target risk, while still allowing the public to effectively protect themselves within and around their homes from mice and rats. These alternatives must be more carefully, and publicly, considered by EPA with the opportunity for dialogue among product makers, users, non-governmental organizations, and the technical experts who have provided global leadership at the same table.

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